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| APPLICATION NO.                                                                                               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------------------------------|-------------|----------------------|-----------------------|------------------|
| 10/766,457                                                                                                    | 01/28/2004  | Carina Horn          | RDID 03021 US (21395) | 3170             |
| 7590 05/24/2007 Brent A. Harris Roche Diagnostics Corporation 9115 Hague Road, Bldg. D Indianapolis, IN 46250 |             |                      | EXAMINER              |                  |
|                                                                                                               |             |                      | GITOMER, RALPH J      |                  |
|                                                                                                               |             |                      | ART UNIT              | PAPER NUMBER     |
|                                                                                                               |             |                      | 1657                  |                  |
| ·                                                                                                             |             |                      | ·                     |                  |
| •                                                                                                             |             |                      | MAIL DATE             | DELIVERY MODE    |
|                                                                                                               |             |                      | 05/24/2007            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                         | Application No.                                                                    | Applicant(s) |  |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------|--|--|--|
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                         | 10/766,457                                                                         | HORN ET AL.  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                         | Examiner                                                                           | Art Unit     |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                         | Ralph Gitomer                                                                      | 1657         |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| 1)🖂                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Responsive to communication(s) filed on <u>04 May 2007</u> .                                                                                                                                                                                            |                                                                                    |              |  |  |  |
| <i>'</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | This action is <b>FINAL</b> . 2b) This action is non-final.                                                                                                                                                                                             |                                                                                    |              |  |  |  |
| 3)[_]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                                                                                                                                         |                                                                                    |              |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                               |                                                                                    |              |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| 5)□<br>6)⊠<br>7)□                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Claim(s) 1-13 and 15-23 is/are pending in the additional state of the above claim(s) 20-23 is/are withdraw Claim(s) is/are allowed.  Claim(s) 1-13 and 15-19 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or | n from consideration.                                                              |              |  |  |  |
| Applicati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ion Papers                                                                                                                                                                                                                                              |                                                                                    |              |  |  |  |
| 9) The specification is objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| 10)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | The drawing(s) filed on is/are: a) ☐ acce                                                                                                                                                                                                               |                                                                                    |              |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| Priority (                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | under 35 U.S.C. § 119                                                                                                                                                                                                                                   |                                                                                    |              |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                         |                                                                                    |              |  |  |  |
| 2) Notice 3) Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) cmation Disclosure Statement(s) (PTO/SB/08) cer No(s)/Mail Date                                                                                             | 4) Interview Summary<br>Paper No(s)/Mail D<br>5) Notice of Informal F<br>6) Other: | ate          |  |  |  |

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The amendment received 5/4/07 has been entered and claims 1-13, 15-19 are considered here.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman.

Ullman (5,445,944) entitled "Methods for Determining Peroxidately Active Substances" teaches in the abstract, detecting a fluorescent signal produced upon cleavage of a compound of the formula F-L-Q. In column 16 last paragraph, the fluorescer may be a coumarin, xanthene, naphthylamine, fluorescein and others. In column 17 last paragraph bridging to column 18, additional fluorescers are shown. In column 20 last full paragraph a number of quenchers are listed including anthraquinones. In columns 21-22 linkers are listed where they may be rings with 5-7 atoms.

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Claims 1-3, 5, 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee.

Lee (5,795,729) entitled "Reductive Energy Transfer Fluorogenic Probes" teaches in column 2 lines 29-33, the fluorescer may be coumarins, fluorescein and resorufins. In column 3 lines 39-62, the reaction may be related to a reductase or an oxidase. And a linker is described. In column 7 last full paragraph, additional linkers are described.

All of the features of the claims are taught by each of the above references.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 6, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman.

See the teachings of Ullman above.

Claim 6 differs from Ullman in that the listed quenchers are not specifically described. And the analytes in claim 15 are not shown by Ullman.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any known quenchers for their known function in view of Ullman who describes a number of quenchers and that any known quenchers can be employed. No unexpected results are seen in the claimed quenchers.

Regarding the analytes in claim 15, Ullman describes an assay that determines peroxidatively related or active substances broadly, and all the analytes in claim 15 can be determined in a reaction where peroxide is generated and determined.

Applicant's arguments filed 5/34/07 have been fully considered but they are not persuasive.

Applicants argue that the claims as amended now recite the detection reagent contains an enzyme and optionally a coenzyme for reducing or oxidizing the analyte which is not taught by the above references. Regarding claim 15, Ullman generally requires a hydroperoxide whereas in the present invention hydroperoxide is to be avoided. The present invention does not require the compounds F-Q to be cleaved to fluoresce.

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It is the examiner's position that the claims are directed to a detection reagent which contains an enzyme where no function for that enzyme is claimed. The above references teach a detection agent where an enzyme is present whether or not the enzyme is part of the detection agent. In Ullman in column 9 last paragraph, it is peroxidase that is detected. In Lee in the abstract, a reductase, oxidase, hydrolase, peptidase or phosphorylase converts the quencher where the quencher then has a reduced activity to quench the reporter. Therefor, in both of the above references an enzyme is present. The present claims do not exclude a hydroperoxide.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Restaures

Ralph Gitomer Primary Examiner Art Unit 1657